

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 2003024-WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/DK2004/000690	International filing date (<i>day/month/year</i>) 08 October 2004 (08.10.2004)	Priority date (<i>day/month/year</i>) 10 October 2003 (10.10.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant COLOPLAST A/S		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 8 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Date of issuance of this report 10 April 2006 (10.04.2006)</td> </tr> <tr> <td style="padding: 2px;">Authorized officer <div style="text-align: center; font-weight: bold;">Simin Baharlou</div></td> </tr> <tr> <td style="padding: 2px;">Telephone No. +41 22 338 71 30</td> </tr> </table>	Date of issuance of this report 10 April 2006 (10.04.2006)	Authorized officer <div style="text-align: center; font-weight: bold;">Simin Baharlou</div>	Telephone No. +41 22 338 71 30
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Telephone No. +41 22 338 71 30				

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 24 JAN 2005

WIPO PCT

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

26 JAN 2005

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/DK2004/000690

International filing date (day/month/year)
08.10.2004

Priority date (day/month/year)
10.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61L15/44, A61K9/127, A61L26/00

Applicant
COLOPLAST AS

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Thornton, S

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2004/000690

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Best Available Copy

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2004/000690

Box No. II Priority

1. ☐ The following document has not been furnished:

☐ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☒ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2004/000690

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial
applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1,9,10 (partly)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 1,9,10 (partly)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/DK2004/000690

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-10
	No: Claims	
Inventive step (IS)	Yes: Claims	1-10
	No: Claims	
Industrial applicability (IA)	Yes: Claims	2-8
	No: Claims	1,9,10

2. Citations and explanations

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Re Item V.

- 1 The following documents are referred to in this communication:
 - D1 : WO 03/047643 A
 - D2 : WO 01/15750 A
 - D3 : WO 92/13565 A
 - D4 : DATABASE WPI Section Ch, Week 199633 Derwent Publications Ltd., London, GB; Class A96, AN 1996-323687 &; JP 08 059438 A (KANEBO LTD) (1996-03-05)
 - D5 : US 5 840 338 A
 - D6 : WO 89/01790 A
 - D7 : DATABASE WPI Section Ch, Week 198538 Derwent Publications Ltd., London, GB; Class A96, AN 1985-233761 &; JP 60 152414 A (POLA KASEI KOGYO KK) (1985-08-10)
- 2 Document D1, which is considered to represent the most relevant state of the art, discloses a wound dressing comprising a therapeutic agent and a barrier layer, which separates the therapeutic agent from the wound fluid. The barrier layer comprises a substrate being degradable by specific proteolytic enzymes, e.g. collagenase in the wound fluid (see D1, page 9, line 10 to page 10, line 27; page 12, line 11-19; claims).

From this, the subject-matter of independent claim 1 differs in that the therapeutic ingredients are present in **liposomes** which comprise releasing means being triggered by a wound constituent and thereby release the therapeutic ingredients of the liposomes.

- 2.1 The subject-matter of claim 1 is therefore novel (Article 33(2) PCT)
The problem to be solved by the present invention may be regarded as to provide a wound dressing capable of target release of one or more therapeutic agents to a wound; to stabilise the therapeutic agent in the wound dressing; and to provide a programmed release of a therapeutic agent.

- 2.2 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) because it has surprisingly been found that by incorporating liposomes into wound dressings a target drug delivery can be achieved by a triggered delivery of therapeutic substances.

Although documents D2, D6, and D7 disclose wound dressings comprising liposomes (see D2, examples, claims; see D6, examples, claims; see D7 abstract) none disclose or teach that by incorporating liposomes into wound dressings a target drug delivery can be achieved by a triggered delivery of therapeutic substances. Document D3 discloses cartilage formation by dressing the site with composition comprising biodegradable matrix, a proliferation agent, e.g. papain, to stimulate proliferation of repair cells in the matrix and transforming factor associated with a delivery system in the matrix to transform the repair cells into cartilage-producing chondrocytes (see D3, page 23, line 23-29; examples 5-7; claims - especially claim 10). D4 discloses a hair treating agent comprising a protease-combined carrier, the protease being preferably thiol protease or a composition comprising a thiol protease or thiol protease-combined carrier wherein the thiol is papain (see D4, abstract). Document D5 discloses loading molecules into safe responsive crosslinked polysaccharide gel networks, e.g. cosmetic formulations comprising papain. However, none of documents D3, D4, D5 disclose a wound dressing. There is no motivation from any of the prior art documents D1-D7 to arrive at the solution disclosed in the subject-matter of claims 1-10 that by incorporating liposomes into wound dressings a target drug delivery can be achieved by a triggered delivery of therapeutic substances.

- 2.3 Claims 2-10 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.